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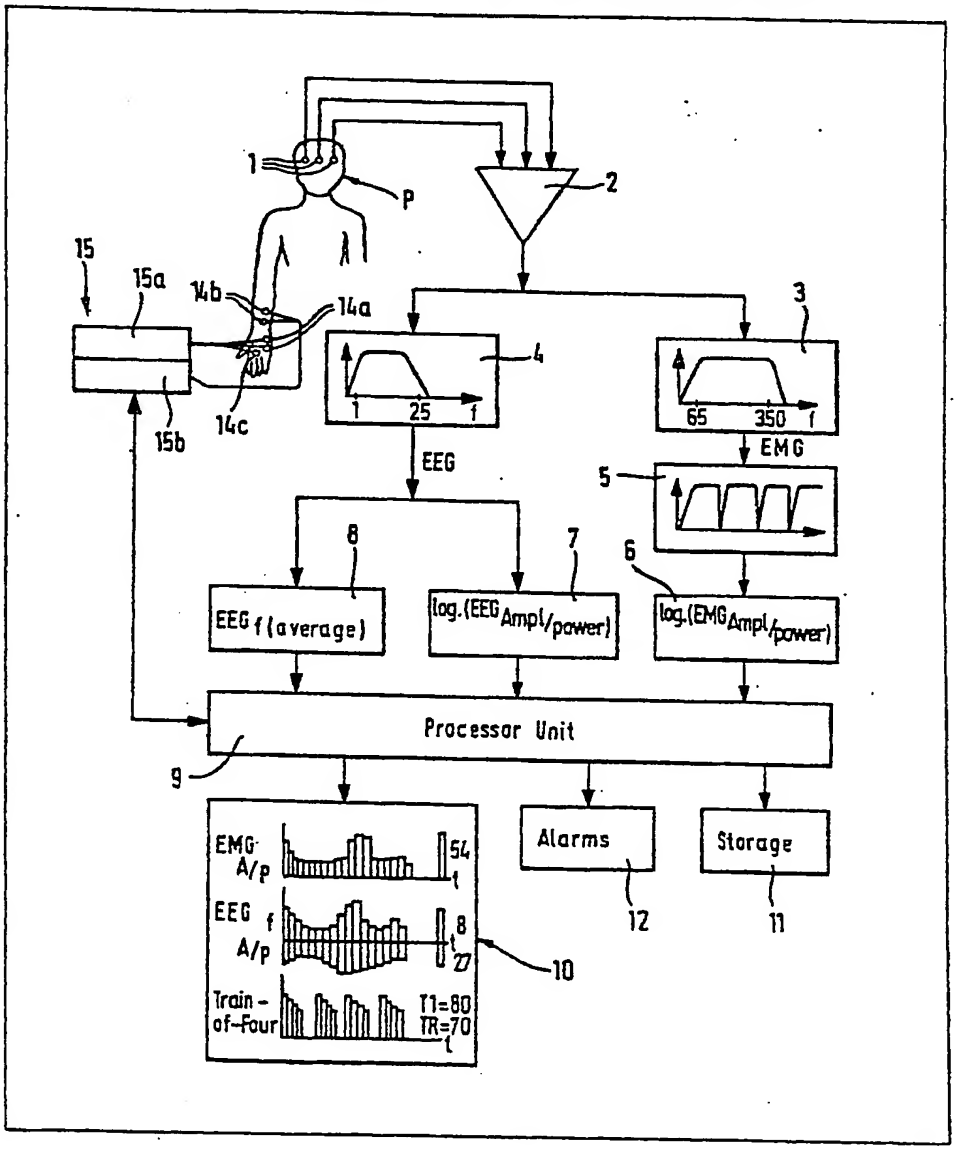
(54) Measuring depth of anaesthesia

(57) A system for monitoring a patient's condition during anaesthesia includes electrode means 1 for detecting bioelectrical signals containing the spontaneous EMG activity of the patient, means 2 for amplifying these signals, means 3, 6 for distinguishing the spontaneous EMG component signals from said signals and for suitably quantifying them e.g. logarithmically as well as separate means 14, 15 for simultaneously measuring the patient's neuromuscular blockage by stimulating a motor nerve by means of electrical impulses and by measuring the muscular reaction by means of EMG. The EGG and EMG signals may be separated from the signals from the electrodes 1 by filtering. Said quantities are recorded and displayed on real-time basis so that the output information of said spontaneous EMG and that of the muscular paralysation measured by stimulation are displayed by a common display unit 10.



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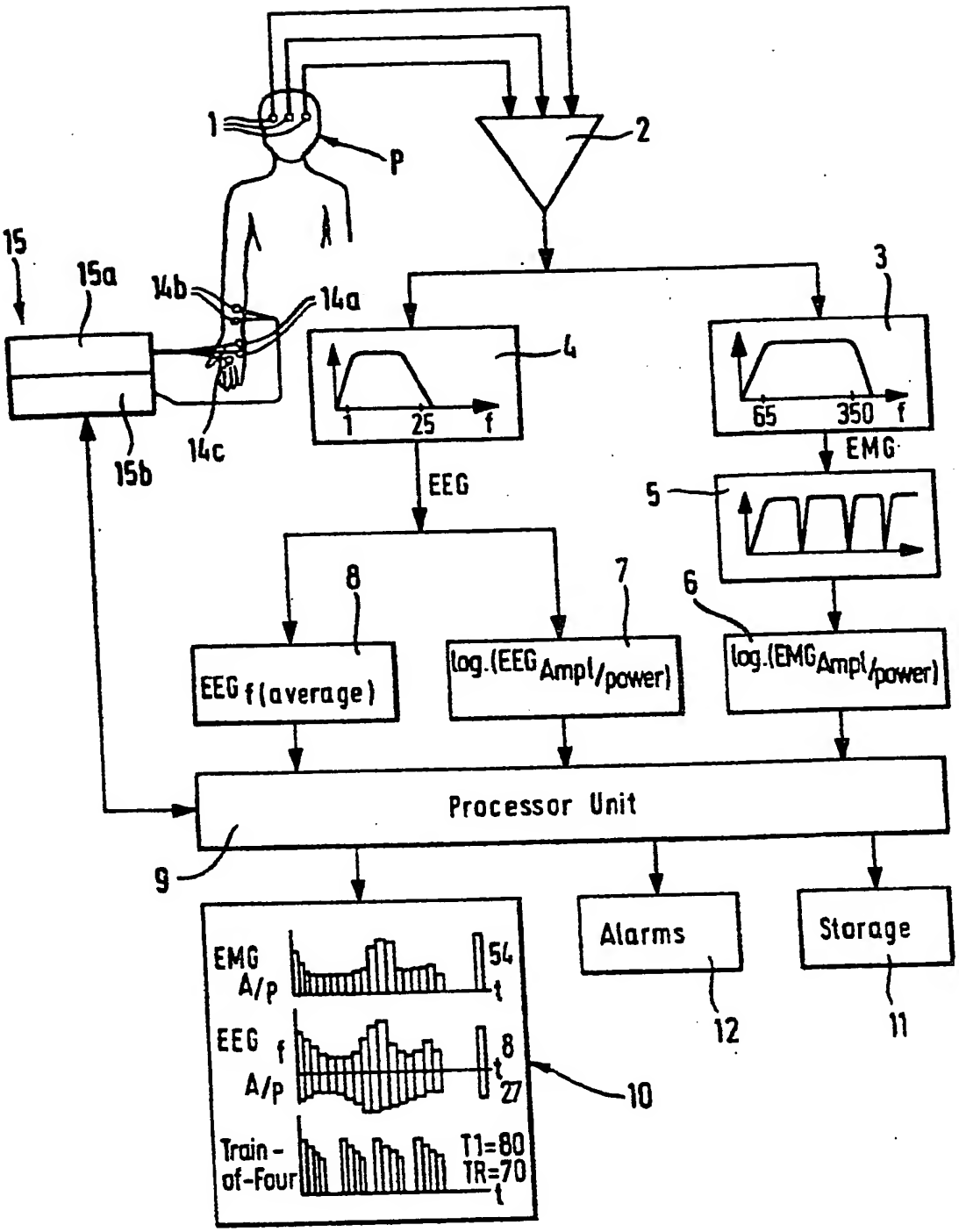

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SPECIFICATION

Measuring and control system

The present invention relates to a measuring and control system for recording and monitoring a patient's condition, especially during anaesthesia in surgical operations.

Monitoring of a patient in surgical operations involves two main criteria: on the one hand, it is necessary to see to it that the depth of a patient's anaesthesia and neuromuscular blockade or paralysation are sufficient for carrying out surgical or like operations, and on the other hand, one must see to it that a patient's paralysation and anaesthetic condition does not become too deep, the hazard being a patient's permanent coma. It is obvious that the more and the quicker it is possible to acquire information correlating as close as possible to a patient's anaesthetic condition and muscular relaxation and the clearer and more readily interpretable the manner in which this information is displayed, the more reliable are the assessments made and the quicker it is possible to undertake the actions which might be required by the situation.

Traditionally, monitoring of the depth of a patient's anaesthesia is primarily effected by monitoring a patient's blood pressure, pulse, electrocardiogram, breathing and pupillary reflexes. One problem with these variables is that generally reliable conclusions cannot be made by thes means the assessment depending on how anaesthetics and paralytics are used at a given time. In addition, these parameters can be modified by a plurality of factors. Examples of these include e.g. possible premedication, a patient's illness, age and general fitness, the location and amount of surgical stimulation, the combined effect of various anaesthetics and paralytics, temperature of the body, the partial pressure of blood's carbon dioxide (Pa_{CO2}). One difficulty is also to relate the changes in these variables to varying dosage of anaesthetics and paralytics. It is also known to assess the depth of anaesthesia by monitoring the EEG waves (electroencephalogram) representing electrical function of the brain for monitoring the electrical activity of a patient's brain. On this basis, a group of researchers from the Duke University Medical Center (Durham, North Carolina, USA) has come up with a means for substantially simplifying the basic information detected and recorded from a patient and important for monitoring during anaesthesia. Since the EEG wave recorded from the area of a patient's skull is often subject to interference produced by muscular activity, the basic idea was that, together with the EEG monitoring effected by means of a recorder, it would be just as possible to utilize and record the occurring EMG activity (electromyogram), representing the electrical action of muscles and later also termed as spontaneous EMG. On the basis of the findings discovered by the group of researchers, EMG monitoring can be advantageously used to indicate sufficient relaxation of a patient, since the recorded EMG reliably reveals a patient's own sensation as to his relaxation, independently of an outside observer's abilities. If then, in connection with monitoring, it is verified that, on the basis of the EMG activity recorded from a patient, relaxation is not sufficient e.g. for surgical operations, the situation can be corrected by administering to the patient either more paralytics or more anaesthetic. On the other hand, EEG monitoring can be used to observe the depth of a patient's anaesthetic condition. (Reference: D. A. Davis, F. F. Klein, M. Harmel, L. Burton, L. Dowell: The Electroencephalomyogram, Quantitation of Depth of Anesthesia, Relaxation and Paralysis, American Society of Anesthesiologists San Francisco, October 20—25, 1979; M. H. Harmel, F. F. Klein, D. A. Davis: The EEMG — A Practical Index of Cordial Activity and Muscular Relaxation, Acta Anaesthesiologia Scandinavica 1978, enclosure 70, pages 97—102).

On the other hand, it has been discovered (B. R. Fink: Electromyoprography in General Anaesthesia, British Journal of Anaesthesia, 1961, 33 pages 555—559) that the activity of abdominal muscles tends to be increased by surgical stimulation and to decrease by the action of anaesthetics and muscular relaxants. The above-mentioned group of researchers has also verified that EMG of the face provides information about a patient's general state of activity and represents a combination of the following parameters having effect on the EMG signal: 1. depth of anaesthesia 2. neuromuscular blockade 3. pain sensations. Thus, it can be summarized that, when said spontaneous EMG during surgical operations is sufficiently low, the depth of a patient's anaesthesia and muscular paralysation can in most cases be considered sufficient. Accordingly, a rise in the amplitude of a spontaneous EMG signal during a surgical operation would cause concern. However, in this case, it is difficult to interpret which of the above parameters is the cause of such rise and whether the patient should be given more anaesthetic, paralytics or analgetic and in which amounts.

An EEG/EMG analyser based on what has been described above is embodied by the above group of researchers by measuring and processing said signals and by producing with a digital voltmeter and recorder from the EEG signal an average frequency and from the EEG and EMG signal an average unidirectional amplitude. From the operator's point of view, such solution is not very perspicuous and a particular difficulty is the monitoring and comparison of the history of displayed quantities.

Apart from this, quite sophisticated recording and display solutions have been developed for just EEG waves. One prior art monitoring system for EEG waves is set forth in US Patent Nr 4 215 697. According to this solution, the amplitude or power and frequency distribution of th EEG signal recorded from the skull of a patient is displayed as a function of tim 3-dimensionally on a video

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monitor as a continuously propagating diagram whereby, in addition to the real-time information, the monitor displays some of the history of the EEG signal. In another prior art EEG monitoring system, on the other hand, a video monitor is used to display the frequency spectrum of EEG amplitude or power in a time representing, second dimension as continuously propagating spot lines, the freshest spot line representing the real-time. The intensity of the actual amplitude or power is solely illustrated by relative brightness of the spots. These prior art systems afford a considerably more illustrative monitoring solution than a mere EEG curve obtained by a recorder. However, such solutions are quite complicated and exp nsive as well as poorly adapted for simultan ous display and monitoring of a plurality of signals.

An object of the invention is to provide a novel and improved patient control system for which the prior art drawbacks are eliminated and which is capable of affording more reliable information about a patient's anaesthetic condition and paralysation, displayed as clearly as possible.

Objects of embodiments of the invention include: from the point of view of a compact operator, a preferable display for a patient's anaesthetic condition and paralysation representing signals to be determined so that the mutually complementary and explanatory quantities are readily comparable; an analogous display for such quantities so as to afford, on the one hand, monitoring of the real-time value of the quantities and, on the other hand, the history thereof, and to provide a display that is illustrative and preferable in view of the use of storage equipment.

According to the present invention, there is provided a measuring and control system for monitoring and recording a patient's condition the system comprising electrode means for detecting and indicating bioelectrical signals containing spontaneous EMG activity of the patient, means for amplifying said signals, means for distinguishing EMG component signals from said signals and for quantifying them in a required manner, means for processing the wave signal information for display, and means for separate measurement of the patient's neuromuscular blockade, substantially simultaneously with said spontaneous EMG activity, by stimulating a motor nerve by means of electrical impulses and by measuring the muscular reaction, said determined quantities being arranged to be recorded and displayed by display means, substantially on a real-time basis.

By employing an embodiment of the present invention, it is possible for an anaesthesiologist to continuously and on real-time basis monitor and compare with each other, on the one hand, a spontaneous EMG measured and determined from a patient and, on the other hand, the muscular paralysation, which will help him in a novel and remarkable manner to distinguish the responses caused by stirring and awakening, from those which result from the lessening of muscular paralysis. In this respect, the compactness and real-time facility of a display are important, since awakening responses are quick phenomena. If electrodes are positioned in the area of a patient's skull and/or neck, it is further possible by means of the same electrodes to monitor the electrical activity of a patient's brain (EEG) and by means of the latter, to ensure that a patient's anaesthetic condition does not become too deep. Thus, on the one hand, the spontaneous EMG, considering the degree of muscular paralysation, warns an anaesthesiologist of awakening responses or too light an anaesthesia and, on the other hand, the EEG warns of metabolic disturbances of the brain, which are associated with too deep an anaesthesia.

In addition to the real-time information, the display means are preferably capable of simultaneously displaying a considerable part of the history of recording events. By selecting for the EMG waves a rather wide band, it is possible to further contribute to the reliability of EMG information, since EMG waves occur within a wide frequency range. Since, on the other hand, it is important to know whether EMG activity in fact exists and not so much at what frequency and absolute amplitude and power, a column diagram and especially one in which the displayed values are logarithmic, serves to illustrate as clearly as possible a patient's activity. The display of logarithms is also preferable in view of the amplitude or power of EEG waves, since the effect of anaesthesia essentially lowers the level of EEG waves, whereby it is of primary interest to detect the relative changes in EEG activity instead of the detection of the absolute values of signal peaks of even high intensity.

EEG waves afford quite a good indicator of a patient's anaesthetic condition, as pointed out above. An indicator preferable for the control is explicitly provided by monitoring an eventual simultaneous major reduction of the values of EEG amplitude or power and EEG average frequency. In practice, an anaesthesiologist, or some other person monitoring in operating theatres a patient's anaesthetic condition, generally has other tasks as well, such as the control of heart operation, blood pressure etc., let alone the actual administration of anaesthetics paralytics to a patient, which is why continuous observation of the equipment is not always possible. In a system of the invention, it is preferable to incorproate in the monitoring an automatic alarm by selecting a suitable limit value for the sum of the values representing said quantities. By providing, in addition, an alarm function for the monitoring spontaneous EMG signals for indicating the insufficient relaxation of a patient, e.g. in view of surgical operation, it is possible to avoid uninterrupted observation of the display equipment.

The invention will now be described in more detail with reference to the single figure of the accompanying drawing which shows a block diagram of an embodiment of the system

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according to the invention.

According to the drawing, the bioelectric activity of a patient P is observed by means of detectors 1. A signal amplified in an isolated preamplifier 2 is passed through band determination means 3 and 4 for the separation of EEG and EMG wave ranges from each other. In reality, the ranges overlap to some extent. As for the extent of the information to be monitored, however, it is perfectly sufficient and for signal processing more simple, to completely separate the ranges to be analyzed from each other, e.g. by selecting the EEG band within the range of 1—40 Hz, in practice 2—25 Hz will be sufficient, and the EMG band within the range of 60—500 Hz, in practice 65—350 Hz will be sufficient.

On factor having effect on the selection of bands is that, since EMG waves can be quite weak, it is necessary to eliminate mains disturbances therefrom prior to the analysis. When the mains frequency is 50Hz (60Hz), the selected EEG ranges can afford the direct elimination of the basic disturbances frequency and its harmonics.

The elimination of mains disturbances from the EEG signal component is effected by means of a filter assembly 5, which can preferably be designed as set out in FI Patent application 811941. Then, by sampling the EMG signal component and by averaging the samples, it is possible to filter the basic disturbance frequency and its odd harmonics from the signal while, at the sam time, the signal is liasing to frequencies lower than the basic disturbance frequency. Thus, the even harmonics can be simply filtered out by means of a high-pass filter. Said liasing of a signal does not in this case affect the monitoring since all that is determined from the EMG signal component is amplitude or power. After the elimination of mains disturbances, the determination of amplitude or power of the EMG signal component and the logarithmication of the values are effected by per se known equipment 6. Accordingly, equipment or means 7 serve to determine amplitude or power of the EEG signal component and also to turn the values logarithmic. Equipment 8 serves to determine average frequency of the EEG signal component.

A processor unit 9 is adapted to pick up samples, preferably representing successive time periods of equal duration, from continuously determined quantities and to process the samples in a manner that they can be displayed by a video monitor or a like display assembly 10 as a continuously propagating, quantitywise column diagram.

An essential part of the system is to measure the neuromuscular blockade from a patient independently of the above-described EMG and EEG signals. This can be effected in a per se known manner by a unit 15, a nerve stimulator 15b giving in repeated cycles successive electric impules to electrodes 14b. One example is to give four pulses at one second intervals ("Train-of-four"), which is repeated at 10—60 sec intervals. The muscular reaction is recorded from electrodes 14a as an EMG amplitude measuring completely independ nt of the above-described spontaneous EMG measuring by employing detector and amplifier means 15a. Electrode 14a is a reference electrode.

Processor 9 controls the operation of means 15 and operates on the received information for display by a video monitor 10. The display can be preferably arranged so that each pulse is matched by its own column, which represents the measured EMG response, the trend of a patient's muscular paralysis being clearly visible. Essential for the interpretation, is, on the one hand, the length of a column that represents the remaining muscular strength and, on the other hand, the ratio between the first and last column of the same period, such ratio illustrating the degree of reduction of muscular strength during repeated stimulation. As for the practical realization of muscular paralysation measuring, reference is made by way of example to the following articles: Lam, H. S., Cass N. M., and Ng, R. C. (1981). Electromyographic monitoring of neuromuscular block. Br. J. Anaesth., 53, 1351. Lam, H. S., Morgan D. L., and Lampard D. G. (1979), January). Derivation of reliable electromyograms and their relation to tension in mammalian skeletal muscles during synchronous stimulation. EEG Clin. Neurophydiol., 46, 72; Ali, H. H. and Savarese, J. J. (1976) Monitoring of neuromuscular function. Anesthesiology, 45, 216. In this way, a separately measured muscular paralysation can be used to interpret which part of the increase of spontaneous EMG activity measured from the face of a patient primarily results from insufficient paralysis and which part from insufficient depth of anaesthesia, since the EMG activity due to algenic stimulation can be controlled by simultaneously monitoring the actual surgical operation.

The system also includes storage means 11 for the information to be displayed and for storing the information to be displayed in a manner such that any part of the history of recorded signal components can be displayed by a video monitor, if desired.

When the screen is filled in the direction of time axis, it is for example, possible to shift the histograms 2/3 backwards on time axis. Thus, if the time axis represents e.g. a 30 minute period, the part of diagram representing the last 10 minutes shifts to the beginning of the time axis to be the first 10 minute period. It should be noted that the column diagram or histogram representing muscular relaxation can be provided with a different time scale from those on said other histograms.

In the displays representing EEG and spontaneous EEG, each column can preferably correspond to the average, measured and calculated for a period of 10 seconds. If desired, the last column can be updated e.g. by one second intervals for continuously receiving practically real-time information. As for the storage means, such arrangement is very advantageous, in other words space saving. The column representing

real-time information can also be slightly spaced from the rest of the histogram, as set out in the drawing. Naturally, the corresponding arrangement can be adapted to the recording of muscular relaxation, e.g. in a manner such that said four pulse cycle is measured more often than one minute intervals, whereby said intermediary outputs better represent the real-time.

The system can also be equipped with alarm means 12 which under the control of the processor unit 9 automatically give out alarm, e.g. a sound or light signal, when one of the quantities to be monitored goes below/exceeds the set limit values. In connection with EEG monitoring, the alarm is preferably arranged to occur when frequency and amplitude/power values simultaneously go below certain limit values. On a monitor, the alarm limit can be visually illustrated by a certain lowest length which is common to the columns indicating said quantities, whereby said length can be visibly marked on a display means, if desired. This alarm system is used to indicate the excessive depth of a patient's anaesthetic condition.

Accordingly, it is possible to provide a certain alarm mode in the monitoring system of spontaneous EMG, said alarm being introduced when a patient's anaesthetic condition and relaxation reach sufficient level for surgical operations and the alarm being given out if the EMG activity, exceeding then a certain limit value, indicating that a patient's anaesthetic condition is insufficient.

If desired, the quantities can also be used to digitally display their real-time value, alarm limit value or the like, as shown in the drawing.

CLAIMS

1. A measuring and control system for monitoring and recording a patient's condition, the system comprising electrode means for detecting and indicating bioelectrical signals containing spontaneous EMG activity of the patient, means for amplifying said signals, means for distinguishing EMG component signals from said signals and for quantifying them in a required manner, means for processing the wave signal information for display, and means for separate measurement of the patient's neuromuscular blockade, substantially simultaneously with said spontaneous EMG activity, by stimulating a motor nerve by means of electrical impulses and by measuring the muscular reaction, said determined quantities being arranged to be recorded and displayed by display means, substantially on a real-time basis.

2. A system in accordance with claim 1 wherein the output information of said spontaneous EMG and that of the muscular paralysation measured by stimulation are displayed by a common display unit.

3. A system in accordance with claim 1 or 2 wherein the muscular reaction is measured by means of EMG.

4. A system in accordance with any preceding claim wherein said EMG signal component is arranged to be displayed in the form of effectiv values, and the system includes filter means for said EMG signal component arranged to filter out the basic frequency of electrical network as well as its harmonic frequencies.

5. A system in accordance with any preceding claim wherein said electrode means are arranged to be positioned in the area of the patient's skull and/or neck so as to detect, in addition, EEG signals arising in the patient, and the system includes means for distinguishing EEG component signals from said bioelectrical signals and for quantifying them in a required manner.

6. A system in accordance with claim 5, wherein said EEG and spontaneous EMG signal components are arranged to be distinguished from each other by means of band determination means so that the band arranged to be selected for said EEG component signal is in the range of 1 to 40 Hz, and that the band arranged to be selected for said EMG component signal is in the range of 60 to 500 Hz.

7. A system in accordance with claim 5, wherein the band for said EEG component is in the range of 2 to 25 Hz.

8. A system in accordance with claim 6 or 7 wherein the band for said EMG component is in the range of 65 to 350 Hz.

9. A system in accordance with any of claims 5 to 8, wherein said EEG signal component is arranged to be displayed in the form of amplitude or effective values and frequency values.

10. A system in accordance with any preceding claim, wherein the determined quantities are arranged to be simultaneously displayed as analogue histograms arranged by quantities in the form of transferable, two-dimensional symbol sequence, so that one dimension is arranged to indicate the quantified value and the other dimension, parallel to the transfer direction of the symbol sequence is arranged to indicate time.

11. A system in accordance with any of claims 5 to 9 and claim 10 when dependent on any of claims 5 to 9 wherein said analogous symbols representing quantified EEG and EMG signal components are arranged to form a column diagram so that the columns for each required quantity are arranged to indicate average values representing chosen periods of time, and that the column diagram further includes a column arranged to indicate real-time value of the quantity.

12. A system in accordance with any one of claims 9, 11 and 10 when dependent on claims 5 to 9 wherein display of said EEG signal is so arranged that th analogue columns describing effective and frequency values are arranged to point in opposite directions while their O-quantities are arranged, at least substantially in alignment with each other, directly or through a narrow intermediary zone.

13. A system in accordance with claim 12 wherein an alarm device is provided, which is arranged to be activated should the joint length of

the columns indicating real value of said EEG effective and frequency values go below a chosen limit value.

14. A system in accordance with any preceding claim wherein an alarm device is provided which is arranged to be activated should the effective values of the EMG signal component exceed a certain limit value.

15. A system in accordance with any preceding claim, wherein the so-called 'Train-of-four' stimulation is arranged to be used for determination of muscular paralysation, whereby four electrical impulses separated from each other by short intervals are given by means of nerve stimulator in repeated cycles, and the measured EMG signal representing electrical reaction of the muscle is arranged to be so displayed that each electrical impulse is represented by a column of its own preferably indicating the integrated value of the measured EMG signal over a shorter period than is the mutual interval between the said four impulses.

16. A system in accordance with any preceding claim, further comprising a digital/analogue converter and storage device for storage of the displayed information in digital form, so that a required part of the history of the detected signal can be re-visualized by means of the said display unit.

17. A system in accordance with any preceding claim, wherein means are provided for providing output of the amplitude or effective values of at least one of the component signals as logarithmic values.

18. A measuring and control system for monitoring and recording a patient's condition, substantially as herein described with reference to the accompanying drawing.

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